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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,144	12/29/2003	Daniel M. Gorman	DX01170K1	4801

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,144	GORMAN, DANIEL M.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-32* is/are pending in the application.

4a) Of the above claim(s) *27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *21-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/03, 3/8/05 & 8/30/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election of Group I invention filed on 20 February 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Note, as applicants pointed out, claim 21 was inadvertently omitted in the restriction requirement in the last Office Action mailed on 1/19/07. The examiner would like to clarify that claim 21 would be included in each of Groups I-V.

Currently, claims 21-32 are pending, and claims 21-26 will be examined to the extent that they read on the elected invention. Claims 27-32 are withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:

Information Disclosure Statement

Applicant's IDSs submitted on 12/29/03, 3/8/05 and 8/30/05 are acknowledged and have been considered. A signed copy is attached hereto.

Priority

This application claims priority to the US application 09/863,818 filed on 5/23/01, and US provisional application 60/206,862 filed on 5/24/00. For the following reasons, the Examiner finds that the present claims 21-26 are not supported in the manner required by 35 U.S.C. 112, first paragraph by the prior applications, thus the present claims are not entitled to the benefit of the filing date of the prior applications.

The priority applications merely discloses the polypeptide sequences of the DCRS9 (same as the present SEQ ID NO:12), and indicates that it is a human cytokine receptor. However, the prior applications fails to provide any specific and substantial utility for the receptor polypeptide of DCRS9, and provides no guidance or working examples to teach how to used said polypeptide. There is no indication in the priority applications that the DCRS9 is a

member of IL-17 receptor family, nor that IL-17C is the ligand of the DCRS9. Therefore, the Examiner is not able to establish that the priority document satisfies the enablement requirement of 35 U.S.C. 112, first paragraph. As such, the claims of the instant application are not entitled to the benefit of the filing date of prior applications listed above.

Accordingly, the subject matter defined in claims 21-26 has an effective filing date of 12/29/03, that of the instant application.

Specification

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Claims

Claim 25 is objected to for encompassing a non-elected subject matter, parts b)-e). The applicant is required to amend the claims to read only upon the elected invention.

Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is indefinite because it is not clear what is meant by "naturally occurring" (human IL-17RE or IL-17C protein). This appears to be product-by-process limitation but it is not clear what distinguishes a "naturally occurring" protein from one that is not. The metes and bounds of the claim cannot be determined. For example, it is not clear whether the IL-17RE protein expressed by a cell transfected with a synthetic DNA encoding the same protein sequence as the IL-17RE isolated from a natural source would be considered to be naturally occurring. The metes and bounds of the claim, therefore, cannot be determined. The claim is further

indefinite for failing to adequately and specifically identify the "IL-17RE protein" and "IL-17C", from which the subject matter of the current invention was derived. The claim merely defines the proteins by arbitrary designations that are not well established terms in the art (IL-17RE, for example; also, IL-17C is called IL-21 or IL-171 by some), and does not require the proteins to have any specific structure or functional property. Further, the specification does not provide the definition of the terms ("a naturally occurring human IL-17RE" and "a naturally occurring human IL-17C"). As such, it is impossible one skilled in the art to understand what "a naturally occurring human IL-17RE" and "a naturally occurring human IL-17C" encompass, the metes and bounds of the claim, therefore, cannot be determined. The claim is further indefinite for the recitation "*modulating an activity*" of a cell because it is unclear what it is meant. Neither the claim nor the specification defines any particular activity in a given cell, nor the meaning of "modulating". As any given cell expressing an IL-17RE may have hundreds of activities of all kinds, the metes and bounds of the claim, therefore, cannot be determined. Also, it is unclear how the blocking binding of the IL-17C to the IL-17RE is related to "modulating an activity of a cell" in the preamble.

Claim 22 is indefinite for the recitation "cytokine expression" because it is unclear which cytokine expression it refers. As it is unclear how many cytokines may exist in nature, the metes and bounds of the claimed mature form cannot be unambiguously determined.

Claim 23 is indefinite for the recitation "a peptide mimetic of an antibody" (part e) because a peptide mimetic of an antibody cannot be "an antigen biding site of an antibody" (independent claim 21) in the same time as they are not the same thing.

The remaining claims are included in this rejection because they are dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a method of inhibiting IL-17C activity in a patient with a condition such as psoriasis with a binding composition, wherein the binding composition comprises an antigen binding site of an antibody to IL-17C of SEQ ID NO:24, does not reasonably provide enablement for claims to a method of *modulating an activity* of a cell expressing IL-17RE with said composition (claim 21, for example), or with a peptide mimetic of the antibody (claim 23, part e)). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The independent claim 21 is directed to a method of modulating an activity of a cell expressing IL-17RE with an antibody binding composition to IL-17C, which blocks binding of the IL-17C to the IL-17RE. The specification teaches that IL-17C of SEQ ID NO:24 was identified as the ligand of DCRS9 (IL-17RE), and that the human DCRS9 is expressed in skin psoriasis (page 55-57). However, the specification fails to disclose any activity of a cell, which can be modulated by blocking IL-17C. As such, one skilled in the art would not know how to use the claimed method, i.e., what activity is needed to be modulated by anti-IL-17C antibody, when and why. The same issue remains in claim 22, for example. Once again, what cytokine expression can be and should be modulated by blocking IL-17C? Therefore, it is absolutely critical for a skilled artisan to know what activity of a cell is associated to the IL-17C so that it can be modulated by antagonizing IL-17C, and why such an activity should be modulated in order to use the claimed method. Such an activity is totally unpredictable. The specification provides no guidance or working example regarding any activity that is associated to the IL-17C. Furthermore, as claim 23 encompasses structurally unidentified peptides (part e)), one skilled in the art would not know how to make the claimed invention. With the exception of the antibodies to the

IL-17C protein of SEQ ID NO:24, an artisan would not know what to test in order to carry on the claimed method.

Due to the large quantity of experimentation necessary to determine what activity or cytokine expression is associated with IL-17C so that it can be and should be modulated by an antibody to IL-17C, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex and completely unpredictable nature of the invention, and the breadth of the claims which encompass modulating unidentified activity of a cell, and structurally unidentified peptides ("a peptide mimetic of an antibody"), undue experimentation would be required of the skilled artisan to make and use the claimed invention.

Claim 23 is further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim encompasses "a peptide mimetic of an antibody" (part e)), which read on any or all functional equivalents of peptides without any structural limitation. Thus, the claim is drawn to a genus of peptides, which is defined only by antigenic specificity, wherein the structure of the antigen (IL-17C) is not well defined. Thus, the claim encompasses a genus of peptides with unknown sequence structure, without any structural limitation, and potentially extreme structural dissimilarity. However, no peptide mimetic of the antibody meeting the limitation of the claim was ever identified or particularly described in the specification.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a "functional characteristic", antigenic specificity (mimetic of an antibody). There is no structural identification of any kind for the encompassed peptides. Thus, the skilled artisan

cannot envision the detailed chemical structure of the encompassed "a peptide mimetic", and therefore conception is not achieved regardless of the complexity or simplicity of the method of making a peptide or chemical molecule. Accordingly, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, in the instant case, only the antibodies to the IL-17C of SEQ ID NO:24, but not the full breadth of the claim (including "a peptide mimetic of an antibody") meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 21-26 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al., US6,569,645.

Chen discloses a newly identified protein termed IL-17C (PRO1122), which amino acid sequence of SEQ ID NO:4 is 100% identical to the present IL-17C of SEQ ID NO:24 (column 4, lines 48-49), and stimulates TNF-α production (column 132, lines 33-36). Additionally, Chen teaches antibodies to the protein, including polyclonal, monoclonal, humanized antibodies (column 84, lines 5-8). Further, Chen teaches that compounds, e.g., antibodies, which bind to stimulating PRO polypeptides and block the stimulating effect of the molecules produce a net inhibitory effect and can be used to suppress the T cell medicated immune response by inhibiting T cell proliferation/activation and/or lymphokine secretion, and blocking the stimulating effect of the polypeptides suppresses the immune response of the mammal (column 78, lines 34-40), and can be used to treat T cell mediated diseases, including, among others, psoriasis (column 92, lines 63-66; and column 93, line 31); and that psoriasis is a T lymphocyte-mediated inflammatory disease (column 96, lines 54-55). Thus, the reference teaches the use of antibodies (including humanized antibodies) to IL-17C for the treatment of diseases such as psoriasis, and therefore, anticipates the present claims. Note, although Chen does not explicitly mention that anti-IL-17C antibodies would inhibit cytokine expression (as claim 22), such would be the inherent property of the method for the treatment.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang Ph.D.
Patent Examiner
AU1646
5/10/07